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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,401	02/23/2004	Peter M. Bonutti	780-A04-002-1	1827
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PAUL D. BIANCO Fleit Gibbons Gutman Bongini & Bianco PL 21355 EAST DIXIE HIGHWAY SUITE 115 MIAMI, FL 33180			EXAMINER TYSON, MELANIE RUANO	
			ART UNIT	PAPER NUMBER
			3773	
			MAIL DATE	DELIVERY MODE
			06/24/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/784,401

Applicant(s)

BONUTTI, PETER M.

Examiner

MELANIE TYSON

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 16-19, 24, and 26-61 is/are pending in the application.
- 4a) Of the above claim(s) 26-31, 45, 51-53, 60 and 61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 16-19, 24, 32-44, 46-50 and 54-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 April 2011 has been entered. Claims 8-15, 20-23, and 25 remain cancelled. Claims 26-31, 45, 51-53, 60, and 61 remain withdrawn from consideration.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

The corrections made to the specification overcome the previous objection and have been entered.

The corrections made to claim 24 overcome the previous objection and have been entered.

The amendments made to the claims overcome the previous 112 rejections and have been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 16-19, 24, 32-44, 46-50, and 54-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. At the time the application was filed, the applicant failed to disclose the elongate body having a "non-expandable portion." Therefore, the limitation is considered new matter. For examination purposes the limitation is interpreted as an elongate body as illustrated in Figure 9. It is recommended the applicant utilize terminology utilized in the specification for defining the body as shown in Figure 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 16-19, 24, 32-42, 44, 46-50, and 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ek et al. (U.S. Patent No. 5,730,747) and Francischelli (U.S. Patent No. 6,699,240 B2).

Ek discloses an apparatus capable of moving a portion of tissue having two tissue sections (see entire document) comprising an elongate body having a non-expandable portion (20; as interpreted above), and a magnetically manipulatable distal end (12), first and second tissue engaging members (42a and 43 respectively; for example, see Figure 2) at the distal end configured to engage tissue (for example, see Figure 4B), the second tissue engaging member movable relative to the first tissue engaging member (for example, see Figures 2 and 2A), a medical implant (52) releasably connected to the first tissue engaging member (via holder 42; for example, see Figures 4B and 4C), a medical implement (50), a pivot connecting the first and second tissue engaging members (for example, see Figure 2), and a biasing member (18 including handles 22 and 24) to spread (open) and to mechanically urge or compress the tissue engaging members. Fukuda fails to disclose a magnetizable material and an electromagnet each in at least one of the tissue engaging members to further urge the second tissue engaging member to the first tissue engaging member.

Francischelli discloses an apparatus capable of moving a portion of tissue having two tissue sections (see entire document) comprising a first and second tissue engaging members (jaws 16 and 18) movable relative to each other. Francischelli teaches a magnetizable material and electromagnet each being disposed in at least one tissue engaging member, wherein the magnetizable material may also be an electromagnet

(for example, see column 2, lines 8-16), wherein generation of a magnetic field would move the tissue engaging members as recited in the claims, the magnetizable material does not dissolve or absorb within the body and thus is considered "permanent" as recited in the claims, the strength of electromagnets are variable, the polarity of electromagnets are reversible and thus may attract or repel each other, the tissue engaging members with the electromagnets may be positioned anywhere along or surrounding the tissue and thus are considered to be "selectably" positionable or "alterable" adjacent tissue, and electromagnets are selectively activatable and deactivatable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate magnets in Ek's tissue engaging members as taught by Francischelli. Doing so would enhance compression between the tissue engaging members (for example, see column 2, lines 4-7), thus reducing the risk of the tissue slipping out from between the tissue engaging members while the medical implant is driven through tissue. With further respect to claim 6, Francischelli inherently discloses a control to control the electromagnet in that a current must be supplied to an electromagnet in order for it to work.

With further respect to claim 16, it is well known to form sutures from bio-resorbable materials. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form Fukuda's suture from a bio-resorbable material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416.

With further respect to claim 38, Ek as modified by Francischelli discloses the claimed invention except for the magnetizable material being iron. However, iron is a well known magnetizable material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the magnetizable material of iron, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ek et al. and Francischelli as applied to claim 40 above, and further in view of Wilkinson (U.S. Patent No. 3,577,991). Ek as modified by Francischelli discloses the claimed invention except for a separate biasing member for spreading the tissue engaging surfaces. Wilkinson discloses an apparatus comprising tissue engaging surfaces (13 and 14) and handles (10 and 11) for compressing the tissue engaging surfaces. Wilkinson teaches a biasing member (15) for holding the tissue engaging surfaces in an open configuration (for example, see column 2, lines 1-4). Thus, it would have been recognized by one of ordinary skill in the art that applying the known technique taught by Wilkinson to the device of Francischelli would have yielded predictable results and resulted in an improved system, namely, a system that would automatically bias the tissue engaging surfaces open, thus enabling a user to operate the tissue engaging surfaces with only a single input to the handles (i.e., compressing the handles together closes the tissue engaging surfaces and releasing the handles automatically spreads the tissue engaging surfaces open).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 16-19, 24, 32-36, 38, 44, 49, 50, 54, 55, and 58 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-26 of U.S. Patent No. 6,719,765 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1-7, 16-19, 24, 32-36, 38, 44, 49, 50, 54, 55, and 58 of the examined application are generic to the device recited in claims 11-26 of the '765 patent. That is, claims 11-26 of the '765 patent fall entirely within the scope of claims 1-7, 16-19, 24, 32-36, 38, 44, 49, 50, 54, 55, and 58 of the examined application, or, in other words, claims 1-7, 16-19, 24, 32-36, 38, 44, 49, 50, 54, 55, and 58 of the examined application are anticipated by claims 11-26 of the '765 patent. Specifically, since a suture passer is a

species of the generic category defined by "an apparatus for moving a medical implement," the device of claims 1-7, 16-19, 24, 32-36, 38, 44, 49, 50, 54, 55, and 58 are anticipated by claims 11-26 of the '765 patent reciting "a suture passer."

Claim 38 would have been obvious over the '765 patent claims. Specifically, iron is a well know magnetizable material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide iron as the magnetizable material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 37, 39-43, 46, 49, 50, 56, 57, and 59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-26 of U.S. Patent No. 6,719,765 B2 in view of U.S. Patent No. 3,577,991 (Wilkinson). Here, claims 11-26 of U.S. Patent No. 6,719,765 B2 recites a device for inserting a suture through tissue comprising electromagnets. The device of claims 11-26 differ from claims 37, 39-43, 46, 49, 50, 56, 57, and 59 herein in that it fails to disclose the presence of a pivot connecting the handles and a biasing member for spreading the tissue engaging surfaces. However, Wilkinson discloses an apparatus for moving an implement comprising tissue engaging surfaces (13 and 14) and handles (10 and 11) for compressing the tissue engaging surfaces. Wilkinson teaches a pivot (12) connecting the handles in order to operate the tissue engaging surfaces and a biasing member (15) for holding the tissue engaging surfaces in an open configuration (for example, see column 2, lines 1-4). Thus, it would have been recognized by one of

ordinary skill in the art that applying the known technique taught by Wilkinson to the device of the '765 patent claims would have yielded predictable results and resulted in an improved system, namely, an operable system that would automatically bias the tissue engaging surfaces open, thus enabling a user to operate the tissue engaging surfaces with only a single input to the handles (i.e., compressing the handles together closes the tissue engaging surfaces and releasing the handles automatically spreads the tissue engaging surfaces open).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose telephone number is (571)272-9062 and e-mail address is Melanie.tyson@uspto.gov. The examiner can normally be reached on Monday through Thursday 8-7 (IFP).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Tyson/

Primary Examiner, Art Unit 3773

June 21, 2011